JACK METCALF
2d District, Washington

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Congress of the United States
House of Representatives
Washington, DC 20515–4702

COMMITTEE ON BANKING AND FINANCIAL SERVICES
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CHAIR, REPUBLICAN HOUSING OPPORTUNITY CAUCUS

REPUBLICAN POLICY COMMITTEE

The Honorable William S. Cohen
Secretary of Defense
The Pentagon
Washington, DC 20301-1010

May 16, 2000

Dear Secretary Cohen:

We are writing to ask for an immediate halt to the Department of Defense (DOD) Anthrax Vaccination Immunization Program (AVIP). The following developments in recent months confirm our concerns regarding this program and its impact on the health and morale of our military service members.

- The Institute of Medicine Committee On Health Effects Associated With Exposures During The Gulf War, in response to a DOD request, provided a letter report entitled "An Assessment of the Safety of the Anthrax Vaccine" on March 30, 2000. In its summary the committee stated:

  > There is a paucity of published peer-reviewed literature on the safety of the anthrax vaccine. The committee located only one randomized peer-reviewed study of the type of anthrax vaccine used in the United States (Brachman et al., 1962). However, the formulation of the vaccine used in that study differs from the vaccine currently in use . . . The committee concludes that in the peer-reviewed literature there is inadequate/insufficient evidence to determine whether an association does or does not exist between anthrax vaccination and long-term adverse health outcomes.

- An internal legal memorandum written in March by two Air Force Reserve judge advocates addressed the following crucial question: *Are orders currently being given to members of the U.S. Armed Forces to submit to anthrax vaccinations consistent with federal law?* In summary, the response stated:

  > Orders currently being given to members of the United States Armed Forces to submit to anthrax vaccinations are illegal because they contradict the express

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terms of Presidential Executive Order 13139 and 10 U.S.C. Section 1107 (1999). Because the anthrax vaccine is being used in a manner inconsistent with both its original licensing and for a purpose for which it has never been tested, the vaccine is properly considered an Investigational New Drug under Food and Drug Administration ("FDA") regulations and federal court decisions. Both the Executive Order and the statute mandate that informed consent is a prerequisite to all vaccinations with an Investigational New Drug. It is undisputed that service members are not giving their informed consent to the vaccination process.

- On March 22, 2000 the Inspector General, Department of Defense issued an "Audit Report on Contracting for Anthrax Vaccine (Report No. D-2000-105). It documents troubling financial management practices and multiple deficiencies cited by FDA that continue to compromise the program.
- The House Subcommittee on National Security, Veterans Affairs, and International Relations issued an oversight report on February 17, 2000 entitled, "The Department of Defense Anthrax Vaccine Immunization Program: Unproven Force Protection." The report was approved and adopted by the full Committee on Government Reform. After a thorough review of current relevant scientific data and compelling testimonies, the Subcommittee made the following recommendations in brief:

> (1) The force-wide, mandatory AVIP should be suspended until DOD obtains approval for use of an improved vaccine. To accomplish this: (2) DOD should accelerate research and testing on a second-generation, recombinant anthrax vaccine; and, (3) DOD should pursue testing of the safety and efficacy of a shorter anthrax inoculation regimen; and, (4) DOD should enroll all anthrax vaccine recipients in a comprehensive clinical evaluation and treatment program for long term study.

In addition, the Subcommittee also recommended:

> (5) While an improved vaccine is being developed, use of the current anthrax vaccine for force protection against biological warfare should be considered experimental and undertaken only pursuant to FDA regulations governing investigational testing for a new indication.

(It is important to note that this recommendation concurs with the Senate Report 103-97, prepared for Senator John D. Rockefeller and the Senate Committee on Veterans' Affairs in 1994. After a review of the scientific data it concluded, "The vaccine should

therefore be considered investigational when used as a protection against biological warfare.")

- The American Public Health Association Governing Council adopted a policy statement November 10, 1999 urging the DOD to "delay any further immunization against anthrax using the current vaccine or at least to make immunization voluntary." They also called on the DOD to create a commission of military and non-military public health experts ". . . to review the evidence for effectiveness and safety of the current vaccine and the time at which an improved vaccine may be available, and to make recommendations about the continuation of the current immunization program."
- The General Accounting Office (GAO) presented testimony on October 12, 1999 before the House Committee On Government Reform on Anthrax vaccine safety and efficacy issues. The report summary includes the following statements:

  > (a) No studies have been done to determine the optimum number of doses of the anthrax vaccine. (b) The long-term safety of the licensed vaccine has not been studied. (c) Since DOD's mandatory inoculation program began in 1998, DOD has conducted two efforts to actively collect data on the short-term safety of the vaccine ... According to the data gathered in both efforts, a higher proportion of females reported reactions to the anthrax vaccine than did their male counterparts. (d) There has been no specific study of the efficacy of the licensed vaccine in humans. Rather, its efficacy in humans has been inferred from other data... (e) Until 1993, FDA inspectors did not inspect the MDPH facility where the anthrax vaccine was made. According to FDA, access was not granted because its inspectors had not been vaccinated against anthrax. DOD conducted inspections, however, and identified deficiencies during a March 1992 inspection, including the absence of stability studies...FDA's subsequent inspections of the production facility in 1997 and 1998 found a number of deficiencies...The facility received warning letters from FDA, including one in March 1997 stating its intent to revoke the facility's license.

- Anecdotal evidence continues to grow of severe, adverse systemic reactions in recipients of the vaccine as demonstrated by congressional testimonies and other sources.

It is clear the AVIP program, while well-intended, is a flawed policy that should be immediately stopped and re-examined in light of the growing preponderance of evidence challenging the DOD's position. We ask that you take immediate action to suspend the AVIP until DOD complies with the recommendations of the Subcommittee on National Security, Veterans Affairs, and International Relations, House Committee on Government Reform as contained in its February 17, 2000 report.

Sincerely,

Jack Metcalf

Jack Metcalf

Christopher Shays

Christopher Shays

Bob Filner

Bob Filner

Ben Gilman

Ben Gilman

Dan Burton

Dan Burton

Peter DeFazio

Peter DeFazio

Nick Rahall

Nick Rahall

George Nethercutt

George Nethercutt

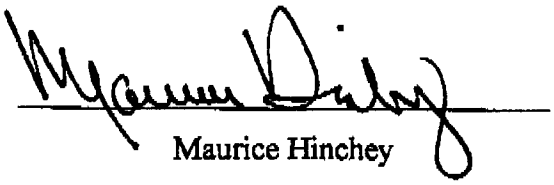
Cynthia McKinney

Cynthia McKinney

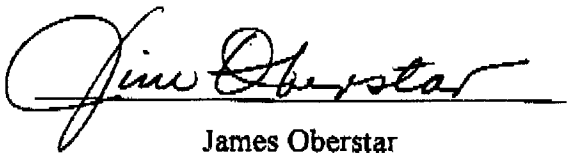
Ron Paul

Ron Paul

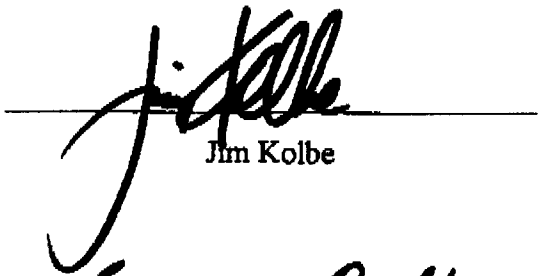
Dana Rohrbacher



Maurice Hinchey

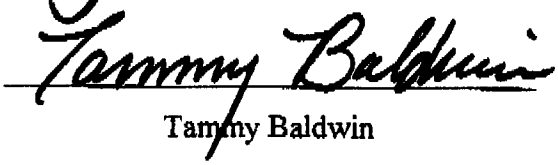


James Oberstar

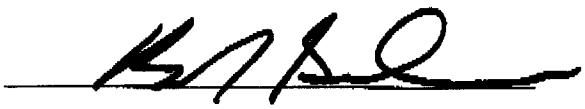


Jim Kolbe

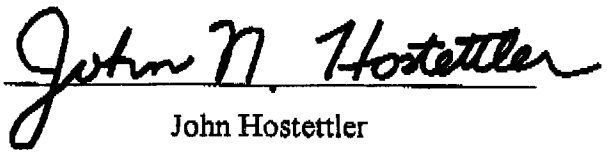
Bob Barr



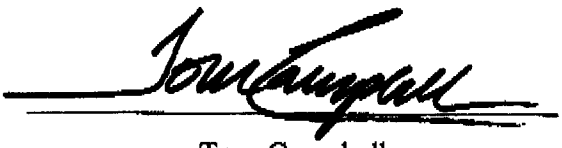
Tammy Baldwin



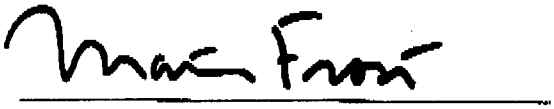
Bernard Sanders



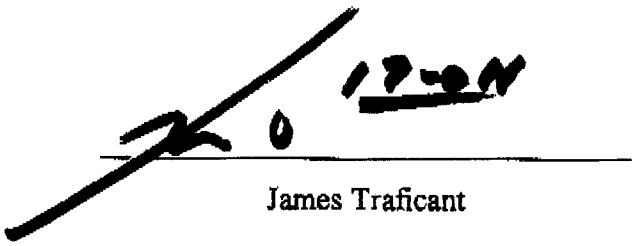
John Hostettler



Tom Campbell

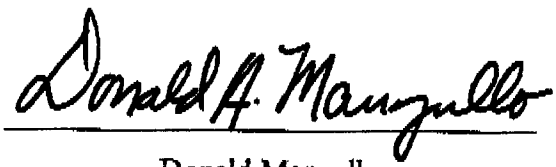


Martin Frost

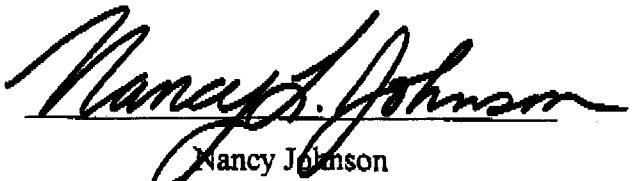


James Traficant

Rick Hill



Donald Manzullo



Nancy Johnson

Richard Baker

Lincoln Diaz-Balart

Mark Souder

John Conyers,

Helen Chenoweth-Hage

Donna Christensen

Charles Taylor

Ron Klink

Robert E. "Bud" Cramer, Jr.

Christopher H. Smith

Bud Shuster, M.C.

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PERSONNEL AND
READINESS

May 16, 2000

The Honorable Dan Burton
U.S. House of Representatives
Washington D.C. 20515

Dear Mr. Burton:

The Department has received your recent letter in which 34 of your colleagues joined you in requesting a halt to the Anthrax Vaccine Immunization Program. I have been asked to respond for Secretary Cohen. I respectfully cannot agree to such a request. While I know that you and your colleagues are motivated by concern for our service members all over the world, I cannot comply because I, too, have that same concern for these brave and patriotic men and women. To suspend the program would place thousands of these fine men and women in a vulnerable position where they would go to work every day in areas of the world where potential adversaries possess the ability to deliver deadly weaponized aerosolized anthrax at any moment. I have enclosed a fact sheet responding to the points cited in your letter.

Anthrax is a deadly biological warfare agent that at least ten nations including North Korea and Iraq are known to possess or have in development. If an individual inhales aerosolized anthrax, there is little chance of survival from this devastating disease. Antibiotics exist, but they must be taken before symptoms develop. However, the chance of that is minimal since aerosolized anthrax is colorless, odorless, tasteless and very difficult to detect. By the time we determine an attack has occurred, it would most likely be too late.

Suspension of the program would recklessly jeopardize the safety of the very people for whom you are concerned. Knowing that the threat exists and that we have a safe and effective FDA approved vaccine available, the Department would be irresponsible if it suspended the program. This FDA approved vaccine has also been validated by the Centers for Disease Control and the National Institutes of Health. The threat is so serious that our Commanders-in-Chief in Korea and Southwest Asia are adamant in their insistence that all of their forward-deployed forces and all inbound personnel be vaccinated. This is a force protection matter that we take very seriously. We would not want to endanger any person by sending them in harms way without protection from this deadly threat.

I realize your letter is well intended. However, I know there is a well-documented threat that is more real today than ever. I know that a lot of erroneous data has been presented by individuals and groups opposed to the Department's inoculation program. I know that sensational stories have been told about anthrax reactions, the overwhelming majority of which are not true. When you administer over 1.7 million doses of vaccine to over 440,000 people, some will get sick, for some reason, inevitably, at some point in time. Although opponents to the inoculation program would have you believe otherwise, most of these illnesses are not related to anthrax vaccine. We work to provide the best medical care for all of our sick servicemen and women and we try to determine the cause of every illness. Many illnesses reported by opponents as anthrax reactions have in fact been traced, by both the military and civilian hospitals, to be due to other causes. This includes a case in which a serviceman's picture was projected on the wall during a congressional hearing on anthrax and portrayed as an "anthrax vaccine reaction" victim. In fact, the picture depicted a skin condition completely unrelated to the anthrax vaccine.

In closing, let me share a true story from an earlier era. In 1898, the British were preparing to fight the Boer War. Their senior leadership considered giving all their troops the recently approved Typhoid Vaccine. Opposition arose, some protests were held, some in their Parliament objected, and that vaccine was made voluntary. Fourteen thousand troops elected to take the shot. The troops went to war and 59,000 came down with typhoid. Nine thousand of them died while a perfectly safe and effective vaccine remained on the shelf - unused! We cannot allow the last chapter of the anthrax story to be a BOER War analogy!

Charles L. Cragin
Acting

Anthrax Vaccination Program

- First Point – "The Institute of Medicine says there is insufficient evidence to determine the long term safety of the vaccine."

  Comment– The same IOM report also states in adjacent paragraphs:

  a. "... few vaccines for any disease have been actively monitored for adverse effects over long periods of time."

  and

  b. "To date, published studies have reported no significant adverse effects of the vaccine."

  and

  c. FDA has stated that "the reports on the anthrax vaccine received thus far do not raise any specific concerns about the vaccine."

- Second Point – "Two Air Force Reserve Judge Advocates say that anthrax vaccination are illegal."

  Comment – The two lawyers quoted were assigned as defense attorneys for an Air Force client charged with violating a lawful order to take the vaccine. As such, the lawyers were required to assert a defense. To do this, they prepared these comments as part of their planned defense tactic. The FDA has continually stated that the vaccine is approved and has been since 1970, as such, is not an investigational drug. Any suggestion that these lawyers' work-product is the opinion of the Air Force or the Department of Defense is absolutely incorrect

- Third Point – "The Inspector General, Department of Defense has documented the troubling financial management practices and multiple deficiencies cited by FDA that continue to compromise the AVIP program."

  Comment – The Inspector General did, as it usually does, find areas that needed improvement. They also found, however, that the contractual relief was provided within Federal Acquisition Regulation guidelines. All vaccine being used has been FDA certified for its safety and efficacy.

- Fourth Point – "The House Subcommittee on National Security Veterans Affairs and International Relations recommends that AVIP should be suspended until the DOD obtains approval of an improved vaccine."

  Comment – The current vaccine was approved in 1970, and reevaluated and re-certified by FDA in 1985. DOD has given over 1,700,000 shots to over 440,000 personnel. Only .00008 percent have resulted in loss of duty. Only .00001% or 31people have required hospitalization. Of these 31, only 6 have been determined to, more probably than not, have illnesses which have resulted from anthrax vaccination. These personnel have been granted waivers to not receive future vaccinations. These determinations were made by an independent panel of experts convened by the U.S. Department of health and Human Services.

- Fifth Point – "The American Public Health Association Governing Council urges the DOD to delay any further immunization against anthrax using the current vaccine or at least to make immunization voluntary."

  Comment – A reading of that association's 17th Edition of the American Public Health Association's Control of Communicable Diseases Manual (James Chin, MD, MPH editor) specifies a preventive measure for exposure to anthrax is to "immunize high risk persons with a cell-free vaccine prepared from a culture filtrate containing the protective antigen. Evidence indicates that this vaccine is effective in preventing cutaneous and inhalational anthrax; it is recommended for laboratory workers who routinely work with B anthrax and workers who handle potentially contaminated industrial raw materials. It may also be used to protect military personnel against potential exposure to anthrax used as a biological warfare agent. Annual booster injections are recommended if the risk of exposure continues."

- Sixth Point – "The General Accounting has stated that the DOD data indicates that women have had a higher rate of negative reactions to the anthrax vaccine."

  Comment – While the rate of adverse reactions is higher for women than men, when scientists of the USAMRIID Ft. Detrick, MD, studied the adverse events of 1,255 men and 335 women, 2% to 4% of men reported events compared to 4% to 7% of women.

  Another study conducted by the Preventive Medicine Division at Tripler Army Medical Center reports overall events or effects by gender as between 4% and 14% for women compared to 2% to 5% men.

  A third study conducted by the Department of Preventive Medicine 121st Evacuation Hospital, Seoul Korea showed an overall rate of events or effects by gender to be 72% to 74% of women and 42% to 44% of men.